PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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BRISBANE QLD 4001

PCT

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing *(day/month/year)*	20 DEC 2005
Applicant's or agent's file reference: 031392PC	**REPLY DUE** within **TWO MONTHS** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2004/001800	21 December 2004	23 December 2003

International Patent Classification (IPC) or both national classification and IPC

INT. CL.

C07H 5/10 (2006.01) ***A61P 7/00*** (2006.01) ***A61P 43/00*** (2006.01)

(continued in Supplemental Box)

Applicant

PROGEN INDUSTRIES LIMITED et al

1. [X] The written opinion established by the International Searching Authority:

   [X] is [ ] is not

   considered to be a written opinion of the International Preliminary Examining Authority.

2. This **2** (second, etc.) opinion contains indications relating to the following items:

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. **If no response is filed by 1 month before the Final Date**, the international preliminary examination report will be established on the basis of this opinion.
Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least **3 months before the Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*.
For an informal communication with the examiner, see Rule 66.6.

4. The **FINAL DATE** by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 23 April 2006

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

[X] The international application in the language in which it was filed:

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of :

- [ ] international search (under Rules 12.3(a) and 23.1 (b))
- [ ] publication of the international application (under Rule 12.4(a))
- [ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed.")*:

[ ] the international application as originally filed/furnished

[X] the description: pages **1-50** as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of

[X] the claims: pages , as originally filed/furnished
pages **54-56** as amended (together with any statement) under Article 19,
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of

[ ] the drawings: pages , as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

- [ ] the description, pages
- [ ] the claims, Nos.
- [ ] the drawings, sheets/figs
- [ ] the sequence listing *(specify)*:
- [ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- [ ] the description, pages
- [ ] the claims, Nos.
- [ ] the drawings, sheets/figs
- [ ] the sequence listing *(specify)*:
- [ ] any table(s) related to the sequence listing *(specify)*:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: **1, 3 (in part)**

because:

☐ the said international application, or the said claim Nos.
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claim Nos. **1, 3 (in part)**

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V **Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims **2-14**	**YES**
	Claims **1**	**NO**
Inventive step (IS)	Claims **2-14**	**YES**
	Claims **1**	**NO**
Industrial applicability (IA)	Claims **1-14**	**YES**
	Claims	**NO**

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this opinion:

D1 WO 1985/000973
D2 US 4459293
D3 WO 2003/038054
D4 Derwent Abstract Accession No 2000-100762/09
D5 Derwent Abstract Accession No 2001-337999/36
D6 Derwent Abstract Accession No 2000-116716/10
D7 WO 1993/024506
D8 WO 1997/018222
D9 Derwent Abstract Accession No 96-116981/12
D10 US 5700918
D11 Chemical Abstracts AN 140:314439
D12 Chemical Abstracts AN 141:54554
D13 Chemical Abstracts AN 138:82903
D14 Chemical Abstracts AN 133:267051
D15 Chemical Abstracts AN 131:322848
D16 Chemical Abstracts AN 129:107414

D11 and D12 are published after the priority date of the application. These documents may become relevant if the priority date of the application is found to be invalid at a later date.

Novelty (N) & Inventive Step (IS)

D1 discloses substituted phenyl-1-thio(poly-O-sulfo)-α(or β)-D-glucopyranosides, cation salts thereof and their use as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes.

D2 discloses bis-[β-D-glucopyranosyl-1-thio (or sulfinyl or sulconyl)-arylene sulfate derivatives, the cation salts thereof, useful as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes.

D4 discloses sulfated galactose compounds (I) and their pharmaceutical preparation.

(continued in Supplemental Box)

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Amended claim 1 is not clear in scope with regards to the following:

(1) it is not clear what radicals are included in the phrase "connected to a different R_1 to R_5 to form a new cyclic group". It is particularly not clear what is envisaged by the term "a new cyclic group".

(2) It is not clear which variable the phrase 'a structure comprising a second unit according to formula II linked via a "Y" group wherein each unit is independently substituted by R7 to R10' at page 55 lines 3-4 defines.

No clear meaning can be given to the scope of claim 1.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: IPC Classification on cover sheet

A61K 31/70 (2006.01)	***A61P 7/02*** (2006.01)	***C07H 11/04*** (2006.01)
A61K 31/7012 (2006.01)	***A61P 29/00*** (2006.01)	***C07H 13/12*** (2006.01)
A61K 31/7016 (2006.01)	***A61P 31/00*** (2006.01)	***C07H 15/04*** (2006.01)
A61K 31/7028 (2006.01)	***A61P 35/00*** (2006.01)	***C07H 15/18*** (2006.01)

Action Date: 01 January 2006

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D5 discloses glucopyranose derivatives of formula (1) useful in the prevention and/or treatment of HIV infections, asthma, atopic dermatitis, and allergic and inflammatory disorders.

D6 discloses glucopyranose derivatives of formulae (I) useful in the treatment of HIV.

D7 discloses glucopyranose or galactopyranosy derivatives of formula I or II (gluand their use in modulating cell mediated immune responses eg for treating psoriasis, asthma, inducing tolerance to antigens.

D8 discloses glucopyranose or galactopyranosy derivatives of formulae I and II with immunosuppressive and tolerogenic activity for modulating cell mediated immune responses especially inflammation eg for treating psoriasis, asthma, dermatitis.

9 discloses mono- or di- saccharide derivatives with galato or gluco stereochemistry.

D13 discloses a galactopyranosyl derivative as a pharmaceutical.

D14 discloses a galactopyranosyl derivative with anti-HIV activity.

D15 discloses a galactopyranosyl derivative with anti-inflammatory activity.

D16 discloses a galactopyranosyl derivative with anti-inflammatory activity.

The proviso in claim 1 excludes the stereochemistry of I to be a gluco or galacto, therefore D1, D2, D4-D9 and D13-D16 no longer anticipate claims 1, 3, 4-10, 12-14.

D10 discloses a moranoline derivative of formula (I) used for treating inflammation, immunopathy, viral infection and cancer. Claim 1 as amended is restricted to oxygen as the heteroatom in the ring of formula I. Therefore D10 no longer anticipates claims 1, 4-10, 12 and 14.

In summary, none of D1, D2, D4-D10 and D13-D16 discloses all of the features of each of the independent claims. Therefore all of the claims are novel and meet the requirements of Article 33(2) PCT with regards to novelty. The subject matter of these claims is also considered not obvious and meets the requirements of Article 33(3) PCT with regards to inventive step.

D3 discloses compounds of Structures I–VI (see Figures 8-11) which can anticipate claim 1 when one of the variables R_1 to R_5 has the value of "connected to a different R_1 to R_5 to form a new cyclic group". As no clear meaning can be given to the term " a new cyclic group", it is considered that the disclosure of D3 anticipates Claim 1. Therefore the subject matter of claim 1 is not new and not inventive and does not meet the requirements of Articles 33(2)-(3) PCT with regards to novelty and inventive step.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.